

**Policy terminated because Medicaid covers codes in the same manner as
Health Choice.**

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1.0 Description of the Procedure, Product, or Service

This policy addresses two minimally invasive, nephron-sparing surgical procedures using thermal ablation to treat renal cell cancer (RCC). Thermal ablation techniques discussed include those that destroy tissue by heating (e.g., radiofrequency ablation [RFA]) or freezing (e.g., cryotherapy, cryosurgery or cryoablation). Thermal ablation may be performed percutaneously, laparoscopically or through open surgery.

The American Cancer Society estimated that there would be about 57,760 new cases of kidney cancer in the year 2009 in this country. About 12,890 people will die from this disease. These numbers include both adults and children; however, it is very uncommon among people under age 45. Most people with kidney cancer are older adults. Renal cell cancer (RCC) is the most common type of kidney cancer. It accounts for more than nine (9) out of ten (10) cases of kidney cancer. There are five (5) main types of renal cell cancer: clear cell, papillary, chromophobe, collecting duct, and unclassified. Each of these types can be recognized by the way the cells look under a microscope. About eight (8) out of ten (10) cases of renal cell cancer are of the clear cell type. The staging system for renal cell cancer is based on the degree of tumor spread beyond the kidney. RCC has four (4) stages, with subclassifications according to tumor location, lymph node involvement and the presence of metastases. Surgical resection is the mainstay of treatment in RCC. Tumor size, location, and recipient characteristics determine the type of excision (e.g., radical or partial nephrectomy) and approach (e.g., open or laparoscopic approach.)

Improvements in medical imaging techniques have increased the ability to detect small renal tumors, which has prompted the development of less invasive, nephron-sparing surgical procedures. Prognosis drops sharply if the tumor extends outside the kidney capsule, since chemotherapy is relatively ineffective against metastatic RCC.

1.1 Medical Term Definitions

- a. Ablation: the removal or destruction of tissue or an abnormal growth, usually by cutting, burning or freezing; may also refer to a very high dose of chemotherapy or radiation treatment that is calculated to kill a tumor.
- b. Cancer: a malignant tumor of potentially unlimited growth that expands locally by invasion and systemically by metastasis; an abnormal growth that can invade nearby structures and spread to other parts of the body.
- c. Chemotherapy: refers to the treatment of disease by chemical agents; more commonly refers to the use of chemicals that have a specific toxic effect upon cancerous tissue.
- d. Co-morbid: existing simultaneously with and usually independently of another medical condition.

- e. **Kidney:** one of a pair of organs located in the right and left side of the abdomen which clear "poisons" from the blood, regulate acid concentration and maintain water balance in the body by excreting urine. The kidneys are part of the urinary tract. The urine then passes through connecting tubes called "ureters" into the bladder. The bladder stores the urine until it is released during urination.
- f. **Kidney Capsule:** a thin layer that covers the outer surface of the kidney (similar to the red peel of an apple).
- g. **Laparoscopic:** using an instrument in the shape of a tube that is inserted through the abdomen to give an examining doctor a view of the internal organs.
- h. **Metastases:** transmission of pathogenic microorganisms or cancerous cells from an original site to one or more sites elsewhere in the body, usually by way of the blood vessels or lymphatics; all malignant tumors are capable of metastasizing.
- i. **Metastatica:** transfer of disease from one organ or part of the body to another not directly connected with it.
- j. **Nephrectomy:** surgical removal of a kidney.
- k. **Nephron:** the anatomical and functional unit of the kidney.
- l. **Percutaneous:** performed through the skin.
- m. **Prognosis:** the prospect of survival and recovery from a disease as anticipated from the usual course of that disease or indicated by special features of the case (i.e., the prognosis is poor because of the accompanying cardiovascular disease).
- n. **Renal:** pertains to the kidneys.
- o. **Tumor:** a new growth of tissue in which the multiplication of cells is uncontrolled and progressive; called also neoplasm.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary **AND**

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Cryoablation or radiofrequency ablation of renal cell carcinoma may be covered by the NC Health Choice Program when it is determined to be medically necessary because the following medical criteria are met.

- a. Either cryoablation or radiofrequency ablation of renal cell cancer may be considered medically necessary to treat localized renal cell carcinoma that is no more than four (4) cm in size when either of the following criteria are met:
 1. Preservation of kidney function is necessary (i.e., the recipient has one kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60mL/min per m²) and standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen kidney function;
 2. Recipient is not considered a surgical candidate due to comorbid disease; OR
 3. The recipient is at high risk for the development of additional renal cell cancer in the future thus the least invasive nephron-sparing approach is desirable.
- b. Coverage for recipients who do not meet these criteria may be provided only in a covered clinical trial designed to address the comparative efficacy of RFA or cryoablation in otherwise lower risk recipients with standard surgical procedures (e.g. partial or total nephrectomy) over a minimum of two (2) years of follow-up.

3.3 Other Medical Policy Guidelines

Clark, et al (2006) have recommended reporting standards for physicians performing percutaneous thermal ablation of primary renal cell cancer. It is hoped that these reporting standards will serve as a template in the design of clinical trials to further evaluate this technology.

According to the recommendations, potential candidates for thermal ablation fall into two general categories:

- (1) Patients who are poor operative candidates as a result of inadequate renal function and/or comorbid disease and
- (2) Patients at high risk for the development of additional RCC in the future in whom the least invasive nephron-sparing approach is desirable.

Patients in the first category include those with RCC detected in a solitary functional or anatomic kidney in whom surgical resection would likely result in the need for dialysis. Individuals with marginal renal function, who would also have a high likelihood of requiring dialysis after resection, may also be suitable candidates for thermal ablation.

Comorbid disease such as coronary artery disease, cardiomyopathy, or chronic obstructive pulmonary disease may introduce an unacceptably high risk with general anesthesia and make a recipient unsuitable for operative resection. In these patients, percutaneous thermal ablation may be an appropriate alternative.

Patients in the second category include those with genetic syndromes associated with RCC, including von Hippel-Lindau syndrome, hereditary papillary cell carcinoma, or hereditary clear-cell carcinoma. These are patients who are screened for RCC at regular intervals, and therefore an incident RCC may be detected at an early stage. They are also more likely to require eventual nephrectomy, so thermal ablation of early-stage RCC may provide a longer interval before nephrectomy becomes necessary. Patients with synchronous RCC (sporadic or associated with a genetic predisposition) also represent a category of recipients who may benefit from thermal ablation. In these patients, surgical resection of a dominant RCC followed by thermal ablation of the smaller contralateral

RCC followed by close observation may enable a longer period before nephrectomy or partial nephrectomy becomes necessary.

According to Clark, "Percutaneous ablation has the potential to become an established minimally invasive therapy for small RCC. To reach this potential, percutaneous thermal ablation must be supported by compelling randomized, prospective trials comparing it with other nephron-sparing approaches for RCC".

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

Cryoablation or radiofrequency ablation of renal cell carcinoma is not covered when the criteria listed in **Subsection 3.2** are not met, because it is considered investigational. The NC Health Choice Program does not cover investigational services.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for cryoablation or radiofrequency ablation (RFA) of renal cell cancer (RCC).

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
February 29, 2012	Throughout	Policy Termination

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Codes
50250
50542
50592
50593

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital and Outpatient Hospital

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.